intended to constitute an official interpretation of the agreement and proposed Consent Order or to modify in any way its terms.

Donald S. Clark,

Secretary.

[FR Doc. 97–23680 Filed 9–5–97; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Health Care Policy and Research

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Health Care Policy and Research, HHS.

ACTION: Notice.

SUMMARY: This notice announces the Agency for Health Care Policy and Research's (AHCPR) intention to request the Office of Management and Budget (OMB) to allow a proposed information collection of the ''Medical Expenditure Panel Survey Household Component (MEPS HC)—Panels 3 and 4.'' In accordance with the Paperwork Reduction Act of 1995, Pub. L. 104–13 (44 U.S.C. 3506(c)(2)(A)), AHCPR invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by November 7, 1997.

ADDRESSES: Written comments should be submitted to: Ruth A. Celtnieks, Reports Clearance Officer, AHCPR, 2101 East Jefferson Street, Suite 500, Rockville, MD 20852–4908.

All comments will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Ruth A. Celtnieks, AHCPR Reports Clearance Officer, (301) 594–1406, ext. 1497.

SUPPLEMENTARY INFORMATION:

Proposed Project

''Medical Expenditure Panel Survey Household Component (MEPS–HC)—Panels 3 and 4.''

The AHCPR intends to conduct an annual panel survey of U.S. households to collect information on a variety of measures related to health status, health insurance coverage, health care use and expenditures, and sources of payment for health services. Each panel consists of a nationally representative sample of U.S. households who remain in MEPS for two consecutive years of data collection. The first two panels of MEPS began in 1996 and 1997. Panels 3 and 4 of the MEPS–HC begin in 1998 and 1999, respectively. The MEPS–HC is jointly sponsored by the AHCPR and the National Center for Health Statistics (NCHS). It will be conducted using a sample of households selected from households which responded to the National Health Interview Survey (NHIS) sponsored by NCHS. The NHIS is a household survey which collects health related data from approximately 50,000 households and 110,000 people. Due to the Department of Health and Human Services (HHS) efforts to integrate survey data collection activities, the NHIS is used as the sampling frame for the MEPS and several other surveys.

Data to be collected from each household include detailed information on demographics, health conditions, current health status, utilization of health care providers, charges and payments for health care services, medications, employment and health insurance. Subject to AHCPR and NCHS confidentiality statutes, data will be made available through publications, articles in major journals as well as public use data files. The data are intended to be used for purposes such as:

- Generating national estimates of individual and family health care use and expenditures, private and public health insurance coverage, and the availability, costs and scope of private health insurance benefits among Americans;
- Examining the effects of changes in how chronic care and disability are managed and financed;
- Evaluating the growing impact of managed care and of enrollment in different types of managed care plans; and
- Examining access to and costs of health care for common diseases and conditions, prescription drug use, and other health issues.

Statisticians and researchers will use these data to make important generalizations on the civilian non-institutionalized population of the United States, as well as to conduct research in which the family is the unit of analysis.

Method of Collection

The data will be collected using a combination of modes. For example, the AHCPR intends to introduce study participants to the survey through advance mailings. The first contact will provide the household with information regarding the importance and uses of the information obtained. The AHCPR will then conduct five (in-person) interviews with each household to obtain health care use and expense data. Lastly, the AHCPR will conduct one telephone interview with each household to obtain tax and asset information. Data will be collected using a computer-assisted personal interviewing method (CAPI). In certain cases, AHCPR will conduct interviews over the telephone, if necessary. Burden estimates follow:

Initial Number of Respondents: 10,000.

Panel 3: 4800.

Panel 4: 5200.

Number of Surveys Per Respondent: 6.

Average Burden Per Respondent: 9.0 hours.

Estimated Burden Total: 81,100 hours.

Panel 3: 39,050 hours.

Panel 4: 42,050 hours.

Request for Comments

Comments are invited on: (a) the necessity of the proposed collection; (b) the accuracy of the Agency's estimate of burden of the proposed collection of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Copies of these proposed collection plans and instruments can be obtained from the AHCPR Reports Clearance Officer (see above).

Dated: September 2, 1997.

John M. Eisenberg,

Administrator.

[FR Doc. 97–23681 Filed 9–5–97; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on September 25, 1997, 8 a.m. to 4 p.m.

Location: Holiday Inn, Versailles Ballrooms III and IV, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Sharon K. Lappalainen, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will provide advice and recommendations to the agency regarding over-the-counter drugs of abuse testing systems and comment on a draft points-to-consider document for these products. Single copies of the draft points-to-consider document entitled ''Points to Consider for Approval of Home Drugs of Abuse Test Kits'' are available to the public by contacting the Division of Small Manufacturers Assistance, 1350 Piccard Dr., Rockville, MD 20851, 1–800–638–2041, or on the Internet using the World Wide Web (WWW) (http://www.fda.gov/cdrh/draftgui.html).

Procedure: On September 25, 1997, from 9 a.m. to 4 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 18, 1997. Oral presentations from the public will be scheduled between approximately 9 a.m. and 10 a.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 18, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed committee deliberations: On September 25, 1997, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)) relating to present and future agency issues.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 28, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–23729 Filed 9–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA regulatory issues.

Date and Time: The meeting will be held on October 28, 1997, 9 a.m. to 5 p.m., and October 29, 1997, 8 a.m. to 5 p.m.

Location: Sheraton Premiere Hotel at Tysons Corner, conference room 6, 8661 Leesburg Pike, Vienna, VA.

Contact Person: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 12397. Please call the Information Line for up-to-date information on this meeting.

Agenda: On October 28 and 29, 1997, the committee will discuss regulation of interventional mammography under the Mammography Quality Standards Act of 1992.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 26, 1997. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on October 28, 1997. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 26, 1997, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 3, 1997.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 97–23728 Filed 9–5–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 90N–0349]

Draft ''Guidance for Industry: Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers.'' The document is intended as general guidance for manufacturers, investigators, sponsors, and other parties interested in the design, endpoints, and efficacy criteria for clinical trials of hemoglobin- and perfluorocarbon-based oxygen carrier products.

DATE: Written comments may be submitted at any time, however, comments should be submitted by December 8, 1997, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of ''Efficacy Evaluation of Hemoglobin- and Perfluorocarbon-Based Oxygen Carriers'' to (1) the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, or (2) the Drug Information Branch, Division of Communications Management (HFD–210), Center for Drug Evaluation and Research, FDA, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–